SECTION 005
510(k) Summary
[As Required By 21 CFR 807.92(a)]

APR 2 4 2014

A. Sponsor

Submitter's Name: Codman & Shurtleff, Inc.
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B. Date Prepared: January 10, 2014

C. Device Name and Classification:

Proprietary Name: **ENVOY® Distal Access (DA) Guiding Catheter**

Common/Usual Name: Catheter, Percutaneous

Classification Name: Percutaneous Catheter (21 CFR 870.1250), Class II

Product Code: DQY

D. Predicate Devices

This 510(k) submission provides pre-market notification for the ENVOY® Distal Access (DA) Guiding Catheter line extension and modifications. The proposed line extension and modifications have not altered the fundamental technology of the predicate devices or the devices' intended use.

Table 1: Prior 510(k) Clearances

510(k) Number	Date Cleared	Name	Manufacturer	Product Code	Predicate For:
Predicate K120229	02/24/2012	ENVOY® Distal Access Guiding Catheter	Codman & Shurtleff, Inc.	DQY	Intended Use Design Materials Manufacturing Sterilization
Predicate K093184	11/06/2009	ENVOY Guiding Catheters	Codman & Shurtleff, Inc.	DQY	Packaging

E. Device Description

The ENVOY Distal Access (DA) Guiding Catheter is a variable stiffness, braided catheter with a large non-tapered lumen that facilitates the intravascular passage of interventional devices. The distal segment is flexible for navigation into distal vasculature. The catheter has an outer hydrophilic coating on the outer surface that reduces friction during manipulation in the vessel. The lubricious PTFE lined inner lumen is designed to facilitate movement of the guide wires and other devices. A luer fitting located on the end of the catheter hub can be used to attach accessories. The distal section of the catheter is radiopaque to aid visualization under fluoroscopy, and the distal tip is clearly distinguished by a radiopaque marker band which is approximately 3mm from the distal tip. The catheter is available with preshaped tips to facilitate positioning. A peel away introducer is included to facilitate insertion into the sheath.

F. Indications for Use

The ENVOY Distal Access (DA) Guiding Catheter is intended for use in the peripheral, coronary, and neuro vasculature for the intravascular introduction of interventional/diagnostic devices.

G. Summary of Technological Characteristics of the Proposed Device to the Predicate Device

The proposed ENVOY® Distal Access (DA) Guiding Catheter is substantially equivalent to the predicate ENVOY® Distal Access (DA) Guiding Catheter. No new technological characteristics are being introduced with the proposed device.

The proposed ENVOY® Distal Access (DA) Guiding Catheter has the same intended use, sterilization process, function, mechanism of action, and clinical utility as the predicate ENVOY® Distal Access (DA) Guiding Catheter, and is similar in regards to design, material, and manufacturing. The proposed ENVOY DA was shown to be substantially equivalent to the predicate device through comparison of indications for use, function, operating principle, bench testing, biocompatibility, and materials. A summary table including characteristics of the proposed device compared with those of the predicate device is provided in **Table 2A and 2B**.

Table 2A: Predicate Comparison Profile		
Description	**Predicate Device: ENVOY® DA Guiding Catheter (K120229)**	**This Submission: ENVOY® DA Guiding Catheter**
Indications for Use	The Envoy Distal Access Guiding Catheter is intended for use in the peripheral, coronary and neuro vasculature for the intravascular introduction of interventional/ diagnostic devices	Same as predicate
Device Description	The ENVOY Distal Access (DA) Guiding Catheter is a variable stiffness, braided catheter with a large non-tapered lumen that facilitates the intravascular passage of interventional devices. The distal segment is flexible for navigation into distal vasculature. The catheter has an outer hydrophilic coating that reduces friction during manipulation in the vessel. The lubricious PTFE lined inner lumen is designed to facilitate movement of the guide wires and other devices. A luer fitting located on the end of the catheter hub can be used to attach accessories. The distal section of the catheter is radiopaque to aid visualization under fluoroscopy, and the distal tip is clearly distinguished by a radiopaque marker. The catheter is available with preshaped tips to facilitate positioning. A peel away introducer is included to facilitate insertion into the sheath.	The ENVOY Distal Access (DA) Guiding Catheter is a variable stiffness, braided catheter with a large non-tapered lumen that facilitates the intravascular passage of interventional devices. The distal segment is flexible for navigation into distal vasculature. The catheter has an outer hydrophilic coating that reduces friction during manipulation in the vessel. The lubricious PTFE lined inner lumen is designed to facilitate movement of the guide wires and other devices. A luer fitting located on the end of the catheter hub can be used to attach accessories. The distal section of the catheter is radiopaque to aid visualization under fluoroscopy, and the distal tip is clearly distinguished by a radiopaque marker **band which is approximately 3mm from the distal tip**. The catheter is available with preshaped tips to facilitate positioning. A peel away introducer is included to facilitate insertion into the sheath.
Product Code	DQY	Same as predicate
Classification	21 CFR 870.1250, Class II	Same as predicate
Length/ Working Length (cm)	95cm & 105cm	Same as predicate
Catheter Inner Diameter	0.071" (1.8mm)	Same as predicate
Catheter Outer Diameter	6.0F (0.082"/2.0mm)	Same as predicate
Shapes	Straight Multi-purpose D (MPD)	Straight Multi-purpose D (MPD) **Multi-purpose C (MPC)**
Transition Segment Length	Standard Transition Segment Length (Standard)	Standard Transition Segment Length Standard **Shorter Transition Segment Lengths for Extra Backup Support XB**
Distal Tip Radiopaque Marker	Pellethane Compound with Radiopaque Filler	Pellethane Compound with Radiopaque Filler & **Metal Marker Band**
Reinforcing Member (Braid)	Stainless Steel	Same as predicate
Liner	PTFE Liner	Same as predicate
Sterilization	EtO	Same as predicate
Product Shelf-Life	1year	**3 years**

Table 2B provides a packaging comparison between the existing ENVOY® Distal Access (DA) Guiding Catheter, the ENVOY Guiding Catheter and proposed ENVOY® Distal Access (DA) Guiding Catheter.

Table 2B: Predicate Packaging Comparison Information			
Description	**Predicate Device Packaging: ENVOY® DA Guiding Catheter (K120229)**	**Predicate Device Packaging: ENVOY® Guiding Catheter (K093184)**	**This Submission: Proposed Device Packaging ENVOY® DA Guiding Catheter**
Dimensions			
Pouch Size	49.21" x 3.95"	46.5" x 4.0"	**49.91" x 4.09"**
Carton Size	47"x 4" x 0.75"	47" x 4" x 0.75"	Same as K120229
Mounting Card	46"x 2.75" x 0.012"	42.75" x 2.687"	Same as K120229
Material			
Pouch Material	Top Web: MRM4820PU (RLE-005) 48GA PET/.002 LDPE Bottom Web: Uncoated 1073B Tyvek	Top Web: MRM002075 (M-2075) 48GA PET/.002 LDPE Bottom Web: Uncoated 1073B Tyvek	Same as K093184
Carton Material	.024" Clay Coated Solid Bleached Surface	.024" Clay Coated Solid Bleached Surface	Same as K120229
Mounting Material	0.012" Clay Coated Solid Bleached Sulfate	Clay Coated Solid Bleached Sulfate	Same as K120229
Sterilization			
Sterilization	EtO	Same	Same as predicate
Shelf-Life			
Packaging Shelf-Life	1 year	3years	Same as K093184

H. Summary of Nonclinical Testing

The proposed ENVOY® Distal Access (DA) Guiding Catheter has the same intended use, sterilization process, function, mechanism of action, and clinical utility as the predicate ENVOY® Distal Access (DA) Guiding Catheter, and is similar in regard to design, material, and manufacturing. The testing conducted to assess the line extension and modifications include performance assessments per the following recognized standards:

Table 3: Performance Standards	
Standard/Guidance/Directive	**Description**
BS EN ISO 11607- 1: 2009	Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials. Sterile Barrier Systems and Packaging Systems
BS EN ISO 11135-1: 2007	Sterilization of Healthcare products Ethylene Oxide: Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices
BS EN ISO 10993-7: 2008	Biological Evaluation of medical devices: Ethylene oxide sterilization residuals – Part 7
BS EN ISO 10555-1: 2009	Sterile. single use intravascular catheters Part 1: General requirements; Sterile
ISO 594-1: 1986 (E)	Conical fitting with a 6% (Luer) taper for syringes, needles and certain other medical equipment: Part 1 – General Requirements
ISO 594-2 : 1998 (E)	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment: Part 2 – Local fittings
AAMI / ANSI HE75 : 2009	Human Factors Engineering – Design of Medical Devices
BS EN 62366: 2008	Medical Devices. Application of usability engineering to Medical Devices
BS EN ISO 10993-1: 2009	Biological evaluation of medical devices: Evaluation & Testing – Part 1
BS EN ISO 10993-5: 2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
BS EN ISO 10993-4: 2009	Biological evaluation of medical devices Part 4: Selection for tests for interactions with blood
USP <661> (2013)	Containers – Plastic. Physicochemical Tests
ISO 10993-10: 2010	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
ISO 10993-11: 2009	Biological evaluation of medical devices Part11: Test for systemic toxicity
ISO 10993-3: 2009	Biological evaluation of medical devices Part 3: Test for genotoxicity, carcinogenicity, and reproductive toxicity

Bench Testing

Results of verification and validation testing that was conducted on the proposed ENVOY® Distal Access (DA) Guiding Catheter demonstrates that it performs as designed, is suitable for its intended use, is substantially equivalent to the predicate device and therefore, does not raise any new questions of safety and effectiveness. Appropriate testing was identified based on a review of the products' risk analyses and previous validation and verification testing.

The following Verification and Validation tests were conducted to verify the modified design ENVOY® Distal Access (DA) Guiding Catheter:

- Visual Inspection
- Catheter Shape
- Catheter Dimensional Verification
- Tensile Strength Testing
- Hydrophilic Coating Integrity
- System Liquid Leakage Testing
- Delamination of PTFE Liner Testing
- Lateral Stiffness Testing
- Linear Stiffness Testing
- Back-Up Support
- Track Testing
- Sheath Introducer Compatibility
- Hub Luer Taper
- System Air Leakage
- Shaft Peel Strength

The following Packaging Validation Testing was conducted with the proposed ENVOY® Distal Access (DA) Guiding Catheter:

- Visual Inspection
- Dye Leak
- Seal Strength

The following Biocompatibility Testing was conducted with the proposed ENVOY® Distal Access (DA) Guiding Catheter:

- *In Vitro* Cytotoxicity – MEM Elution
- Sensitization – Guinea Pig Maximization
- Intracutaneous/Irritation Reactivity
- Acute Systemic Toxicity

- Material Mediated Pyrogenicity
- Genotoxicity
  - *In Vitro* Bacterial Mutagenicity – Ames Assay
  - *In Vitro* Mouse Lymphoma Assay with extended treatment
  - *In Vivo* Mouse Micronucleus Assay
- Hemocompatibility
  - *In Vitro* Hemolysis – Direct & Extract Method
  - Partial Thromboplastin Time (PTT)
  - Complement Activation C3a & SC5b-9 Assay
  - *In Vivo* Thrombogenicity
- Physicochemical Aqueous Extraction Tests

In addition, the new sterile pouch packaging material was evaluated for *in vitro* cytotoxicity and was tested per ISO 10993-5 (Biological Evaluation of Medical Devices – Part 5: Tests for *in vitro* cytotoxicity.

The following Sterilization Test was conducted with the ENVOY® Distal Access (DA) Guiding Catheter:

- USP Limumus Amebocyte Lysate (LAL) Test – Kinetic Chromogenic Method

I. Animal Testing

No animal studies were required as appropriate verification and validation of the catheter and packaging modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

J. Summary of Clinical testing:

No clinical studies were required as appropriate verification and validation of the catheter and packaging modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

Conclusion:

Based upon the design, materials, function, intended use, and the non-clinical testing performed by Codman it is concluded that the proposed ENVOY® Distal Access (DA) Guiding Catheter is substantially equivalent to the current ENVOY® Distal Access (DA) Guiding Catheter (K120229), and therefore, does not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 24, 2014

Codman & Shurtleff, Inc.
Hannah Foley
Regulatory Affairs Specialist II
325 Paramount Dr.
Raynham, MA 02767-0350 US

Re: K140080
Trade/Device Name: ENVOY Distal Access (DA) Guiding Catheter, 6F, 95cm & 105cm, Straight & XB, MPD & XB, MPC & XB
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 26, 2014
Received: March 27, 2014

Dear Ms. Foley,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if Known): K140080

Device Name: ENVOY® Distal Access (DA) Guiding Catheter

Indications for Use:

The ENVOY® Distal Access (DA) Guiding Catheter is intended for use in the peripheral, coronary, and neurovasculature for the intravascular introduction of interventional/diagnostic devices.

Prescription Use: X **AND/OR** **Over-The-Counter Use:**
(Part 21 CFR 801Subpart D) **(Part 21 CFR 807 Subpart C)**

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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